

21—41.9(198) Drug and feed additives.

41.9(1) Prior to approval of a product label for commercial feed which contains additives (including drugs, other special purpose additives, or nonnutritive additives), the distributor may be required to submit evidence to prove the safety and efficacy of the commercial feed when used according to the directions furnished on the label.

41.9(2) Satisfactory evidence of safety and efficacy of a commercial feed may be:

a. When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in the Code of Federal Regulations, Title 21, or which are “prior sanctioned” or “informal review sanctioned” or “generally recognized as safe” for such use, or

b. When the commercial feed is itself a drug as defined in Iowa Code section 198.3(6) and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the Food and Drug Administration under Title 21 U.S.C. 360(b), or

c. When one of the purposes for feeding a commercial feed is to impart immunity (that is to act through some immunological process) the constituents imparting immunity have been approved for the purpose through the Federal Virus, Serum and Toxins Act of 1913, as amended, or

d. When the commercial feed is a direct-fed microbial product and:

(1) The product meets the particular fermentation product definition; and

(2) The microbial content statement, as expressed in the labeling, is limited to the following: “Contains a source of live (viable) naturally occurring microorganisms.” This statement shall appear on the label; and

(3) The source is stated with a corresponding guarantee expressed in accordance with 41.4(7).

e. When the commercial feed is an enzyme product and:

(1) The product meets the particular enzyme definition defined by the Association of American Feed Control Officials; and

(2) The enzyme is stated with a corresponding guarantee expressed in accordance with 41.4(8).